UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

INDUCTION THERAPIES, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:20-cv-00382-DJH**
	)	*Filed Electronically*
	)	
INGENES, LLC, and	)	
DR. KRISHNAMURTHY GOVINDARAJ	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

The Plaintiff, Induction Therapies, LLC, by and through the undersigned counsel, submits the following as and for its First Amended Complaint against the Defendants, Ingenes, LLC ("Ingenes") and Dr. Krishnamurthy Govindaraj ("Govindaraj"):

PARTIES, JURISDICTION, AND VENUE

A. General Allegations

1. The Plaintiff is a limited liability company organized under the laws of South Dakota and registered to transact business in Kentucky with the Kentucky Secretary of State.

2. The Defendant Ingenes, is a company organized under the laws of Delaware. To the best of Plaintiff's knowledge and belief, its principal office is located at 16192 Coastal Highway, Lewes, DE 19958. Defendant's agent for service of process in is Harvard Business Services, Inc., also located at 16192 Coastal Highway, Lewes, DE 19958.

3. The Defendant Govindaraj is the sole member of Ingenes, LLC, and to the best of Plaintiff's knowledge and belief, resides at 10135 Treble Court, Rockville, MD 20850.

B. Allegations Supporting Personal Jurisdiction

4. At all times relevant hereto and at the time this suit was filed on May 1, 2020, Angelia Inscoe, Plaintiff's sole owner, was a resident of Kentucky. As a result, the Plaintiff was also a resident of Kentucky.

5. At all times relevant hereto, Plaintiff's principal office has been located at 1920 Stanley Gault Parkway, Suite 100, Louisville, Kentucky 40223.

6. At all times relevant hereto, the Plaintiff has maintained its operating bank account with River City Bank in Louisville, Kentucky.

7. This case arises out of an agency relationship created by the FDA 510k Consulting and Submission Agreement (the "Consulting Agreement") attached hereto as **Exhibit 1**.

8. As set forth more fully herein, the contractual relationship at issue in this case was between the Plaintiff and Ingenes.

9. As evidenced by the Food and Drug Administration ("FDA") correspondence attached hereto as **Exhibit 2**, directed to the Plaintiff at its Louisville, Kentucky principal place of business, the parties anticipated from the outset that the services contemplated by the Consulting Agreement would be used in Louisville, Kentucky.

10. Thus, Ingenes is subject to personal jurisdiction in Kentucky pursuant to KRS § 454.210(2)(a)(2) of Kentucky's long-arm statute.

11. As set forth in more detail below, over the sustained course of more than one year, both Ingenes and Govindaraj sent numerous e-mails to the Kentucky plaintiff containing negligent advice and recommendations, as well as unlawful demands for payment of consulting fees that were not contemplated by the Consulting Agreement.

12. As a result of these unlawful demands for payment, Ingenes received tens, if not hundreds, of thousands of dollars in consulting fees beyond the $51,593.00 flat payment contemplated by the Consulting Agreement from the Plaintiff's bank account in Kentucky.

13. Thus, the Defendants' acts and omissions directed toward the Commonwealth caused tortious injury in the Commonwealth, and the Defendants are subject to this Court's personal jurisdiction pursuant to KRS § 454.210(2)(a)(3) and (4) of Kentucky's long-arm statute.

14. Furthermore and finally, the Defendants' sustained course of interactions with the Plaintiff in Kentucky satisfy minimum due process requirements for the exercise of personal jurisdiction and the KRS § 454.210(2)(a)(1) test of "transacting any business in this Commonwealth."

C. Subject Matter Jurisdiction and Venue

15. At the time this Complaint was filed, the Plaintiff was lawfully a citizen of Kentucky, and both Defendants were citizens of states other than Kentucky.

16. The amount in controversy in this dispute exceeds $75,000.00.

17. The Plaintiff therefore agrees with the Defendant's position that this Court has original subject matter jurisdiction of this dispute pursuant to 28 U.S.C. § 1332(a).

18. The United States District Court for the Western District of Kentucky, Louisville Division, is the appropriate venue for this action pursuant to 28 U.S.C. §§ 1391(b)(2) and (3) because (1) a substantial part of the events, acts, and omissions giving rise to this claim occurred in Louisville, Kentucky; and (2) the Defendants are both subject to the personal jurisdiction of this Court, both as more fully set forth in the preceding sub-section.

FACTUAL ALLEGATIONS

19. The Plaintiff, Induction Therapies, LLC, has developed and wishes to market a micro-needling medical device known as a Collagen PIN for use in skincare treatments.

20. The Defendant, Ingenes, LLC, markets itself throughout the United States as a "full-service regulatory and product development consulting firm for … medical devices…"

21. On or about December 26, 2018, the Plaintiff and Defendant entered into the FDA 510k Consulting and Submission Agreement attached hereto as **Exhibit 1**.

22. A 510(k) application is "a premarket submission made to FDA to demonstrate that the device to be marketed is safe and effective, that is, substantially equivalent, to a legally marketed device." To receive premarket approval, applicants "must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims." "Until the submitter receives an order declaring a device [substantially equivalent], the submitter may not proceed to market the device."

23. Pursuant to the Consulting Agreement, the Defendants agreed to perform the following services: (a) "act as a liaison" between the Plaintiff and testing laboratories located in India; (b) "prepar[e] and fil[e] the 510k submission for the Device"; and (c) conduct "Quality Assurance Review of all draft test reports."

24. In exchange, the Plaintiff agreed to pay Ingenes a total consulting fee of $51,593.00 - $1,593.00 for work completed prior to the date of the Contract; a flat $35,000.00 consulting fee for the preparation and submission of the 510(k) application; and a flat $15,000.00 consulting fee for the Quality Assurance Review work.

25. In addition to Ingenes' consulting fee, the Consulting Agreement contemplated that Ingenes would act as an escrow agent or intermediary for all payments to laboratories in India, estimated to total $121,644.00 in the Consulting Agreement.

26. The FDA maintains a database of predicate medical devices known as the "510(k) Database."

27. Because the 510(k) application process involves the comparison of the applicant's medical device to a predicate medical device, the standard of care applicable to FDA consultants like Ingenes and Govindaraj requires them to consult the 510(k) Database and determine the scope of testing used to approve such predicate medical devices – information which is also accessible through the FDA.

28. Thus, following the Consulting Agreement's execution, the scope of testing defined by the Consulting Agreement should not have expanded significantly.

29. However, between December 26, 2018 and February 2020, the scope of testing recommended by the Defendants expanded considerably.

30. By way of example and not limitation, on March 14, 2019 – nearly three months after the Consulting Agreement's execution – Govindaraj advised the Plaintiff that the testing cost for a pig study was $71,084.29. *See* **Exhibit 3**.

31. By this same email, Govindaraj and Ingenes charged Plaintiff an additional $21,325.29 as another "30% consulting fee," even though Ingenes had already agreed to a flat $51,593.00 consulting fee pursuant to the Consulting Agreement.

32. Govindaraj and Ingenes made repeated requests of a similar nature over the ensuing months.

33. Faced with the alternative of jeopardizing its 510(k) clearance, the Plaintiff acceded to these inappropriate and extra-contractual payment requests. However, Plaintiff never waived its right to sue Ingenes and Govindaraj for their tortious and borderline extortionate actions.

34. Between December 26, 2018 and February 28, 2020, the Plaintiff caused its Kentucky banks to send $548,665.50 to Ingenes through 14 separate wire transfers, all requested by the Defendants by separate e-mail correspondence directed to the Kentucky Plaintiff. *See* Wire Transfer Compilation, **Exhibit 4.** The total wire transfers exceeded the amount originally contemplated by the Consulting Agreement by $375,428.50.

35. On December 30, 2019, Defendants submitted an incomplete 510(k) application to the FDA.

36. By May 1, 2020, the Defendants had still not submitted a complete 510(k) application to the FDA, yet they continued to try to strongarm the Plaintiff into paying "consulting fees" well beyond what was originally contemplated by the Consulting Agreement.

37. Under black letter Kentucky law, "[t]he right of a principal to require an accounting of his agent is elementary. … Unless otherwise agreed, there is no discretion as to whether an accounting may be required." *Deaton v. Hale*, 592 S.W.2d 127, 130 (Ky. 1979)

38. The Plaintiff has asked the Defendants to account for the allocation of the payments directed to Ingenes between laboratory tests and consulting payments, but the Defendants have refused to comply with this request.

39. Based on the 30% consulting fee "charged" in **Exhibit 3**, the Plaintiff estimates that the Defendants have received at least $86,637.34 more than the Consulting Agreement permitted.

40. Had Defendants Govindaraj and Ingenes complied with the standard of care applicable to FDA consultants, all tests would have been known up front, the application would

have been completed and submitted long ago, and the Defendants never would have been able to place the Plaintiff in the Catch-22 position the Plaintiff encountered.

41. As a result of the Defendants' misdeeds, the Plaintiff has suffered and will continue to suffer contractual and consequential damages, including the known overpayment of at least $86,637.34 in consulting fees.

COUNT I: ORDINARY NEGLIGENCE
(Against Both Defendants)

42. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

43. Whether or not the relationship rises to the level of a fiduciary relationship, all agents owe their principals – at the bare minimum – a duty of reasonable care related to the subject matter of their agency.

44. The Defendants were agents of the Plaintiff and therefore owed the Plaintiff the duty of ordinary care.

45. By virtue of their actions identified above, including their failure to appropriately investigate the FDA's 510(k) Database, the Defendants violated their duty of ordinary care, resulting in a completely unwarranted and unjustified delay in the filing of the Defendants' 510(k) application.

46. At a minimum, the Defendants' actions were negligent, and other circumstances, including the repeated demands for excess consulting fees, suggest that Defendants' actions may have been the product of a reckless or intentional disregard for the Plaintiff's interests.

47. The delayed 510(k) filing has caused harm to the Plaintiff. In addition to being unable to sell their medical device, resulting in lost sales, other competitors have entered the market during the intervening time period.

48. Thus, as a direct and proximate result of the Defendants' negligent, reckless, or intentional misdeeds, the Plaintiff has been damaged in an amount to be determined at trial and is entitled to recover compensatory damages.

COUNT II: BREACH OF THE DUTY OF GOOD FAITH/ BREACH OF FIDUCIARY DUTY (Against Both Defendants)

49. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

50. As a baseline, Kentucky courts require agents to comply with a baseline "business obligation of good faith and fair dealing." *See In re Sallee*, 286 F.3d 878, 892-93 (6th Cir. 2002).

51. Moreover, in situations where a principal has reposed a special trust or confidence in the agent, the agent also occupies a position of fiduciary responsibility and must place the principal's interests above his, her, or its own.

52. Here, circumstances indicate that just such a special, confidential relationship existed. Among other reasons, (a) Defendants held themselves out and Plaintiff relied on them as the subject matter experts in the field of FDA regulation; (b) Plaintiff provided confidential information related to its medical device to Defendants; and (c) Plaintiff entrusted funds that belonged to third parties to the Defendants for distribution to those third parties.

53. In other words, the relationship between the Plaintiff and Defendants most closely resembled the relationship between attorney and client, understood to be one of the traditional fiduciary relationships, as opposed to a run-of-the-mill arm's-length business relationship.

54. Whether arising out of a heightened fiduciary obligation or the narrower baseline obligation of good faith and fair dealing, the Defendants certainly had obligations to (a) provide

sound, reasonable advice to the Plaintiff that was not slanted by the Defendants' own self interest and (b) deal with the Plaintiff fairly and honestly.

55. By virtue of the acts and omissions described above, the Defendants breached their obligations to the Plaintiff.

56. As a result, the Plaintiff has been damaged in an amount to be determined at trial.

COUNT III: RIGHT TO AN ACCOUNTING/ BREACH OF CONTRACT
(Against Ingenes)

57. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

58. During the course and scope of its agency relationship with the Plaintiff, Ingenes received property – to wit, cash payable to third parties – that did not belong to Ingenes.

59. As a matter of black letter Kentucky law, "[t]he right of a principal to require an accounting of his agent is elementary. … Unless otherwise agreed, there is no discretion as to whether an accounting may be required." *Deaton v. Hale*, 592 S.W.2d 127, 130 (Ky. 1979).

60. The Plaintiff has demanded but Ingenes has refused to provide such an accounting.

61. Thus, the Plaintiff is entitled to the immediate entry by the Court of an Order requiring the Defendants to account for the receipt and disposition of all funds received from the Plaintiff, including but not limited to copies of checks or wire transfer confirmations, deposit slips, and invoices from labs based in India supporting the disposition of funds.

62. Based on records presently available to the Plaintiff, to wit the unjustified demands for a 30% consulting fee not contemplated by the Consulting Agreement, the Plaintiff can reasonably infer that Ingenes has received at least $86,637.34 they were not contractually entitled to receive.

63. Ingenes' actions constitute a breach of contract entitling the Plaintiff to recover (a) the $86,637.34 overpayment; (b) any other overpayment revealed by the accounting; and (c) consequential damages in an amount to be determined at trial.

COUNT IV: UNJUST ENRICHMENT
(Against Ingenes)

64. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

65. Plaintiff pleads this claim as an alternative to Count III.

66. By virtue of the conduct described herein, Ingenes received funds to which it was not entitled by employing means that were unjust and inequitable.

67. Ingenes would be unjustly enriched if it were permitted to retain these funds and should be required to disgorge them to the Plaintiff.

COUNT V: CONVERSION
(Against Ingenes)

68. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

69. Ingenes retains the Plaintiff's file, including proprietary information regarding the Collagen PIN, test results for which the Plaintiff paid, and other property rightfully belonging to the Plaintiff.

70. The Plaintiff has made a demand for the return of the property, but Ingenes has refused to return it.

71. Ingenes' refusal to return the Plaintiff's property is willful, improper, and driven by the very same motive that has informed Ingenes' decisions throughout the parties' relationship –

to receive substantial fees well above and beyond those originally set forth in the Consulting Agreement.

WHEREFORE, the Plaintiff respectfully demands the following relief:

A. On Counts I and II of the Complaint, a judgment against both Defendants, jointly and severally, for compensatory and punitive damages;

B. On Counts III through V of the Complaint, a judgment against Ingenes for compensatory and punitive damages;

C. On Count V of the Complaint, temporary and permanent injunctive relief requiring Ingenes to return the Defendants' confidential and proprietary information;

D. Pre- and post-judgment interest at the applicable legal rates;

E. An award of Plaintiff's reasonable costs and attorney's fees to the extent permitted by applicable law;

F. Trial by jury on all issues so triable; and

G. Any and all other relief, legal or equitable, to which the Plaintiff may appear entitled.

Respectfully submitted,

/s/ Christopher B. Rambicure

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CERTIFICATE OF SERVICE

I certify that on July 3, 2020, I served a copy of the foregoing upon all counsel of record by electronic means through the Court's CM/ECF system.

/s/ Christopher B. Rambicure
Counsel for the Plaintiff